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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/542,127	12/20/2005	Yamini Bhushan Tripathi	4544-052144	8251

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EXAMINER

TATE, CHRISTOPHER ROBIN

ART UNIT	PAPER NUMBER
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1655

MAIL DATE	DELIVERY MODE
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08/29/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/542,127	Applicant(s) TRIPATHI, YAMINI BHUSHAN	
	Examiner Christopher R. Tate	Art Unit 1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

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DETAILED ACTION

Claims 1-6 are presented for examination on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-6 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for treating atherosclerosis and hyperlipidemia and/or reducing the risk thereof, does not reasonably provide enablement for preventing these clinical conditions. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Applicants have reasonably disclosed/demonstrated (thru *in vivo* studies using rabbit models) that the instantly claimed polyherbal formulation is useful as a therapeutic preparation in treating atherosclerosis and hyperlipidemia (as well as reducing the risk thereof). The prior art also recognizes that at least some of the claimed herbals are useful for such purpose (as well as reducing the risk thereof) - see, e.g., art cited in the attached PTO-892. However, the claims also encompass using the claimed polyherbal formulation to prevent atherosclerosis and hyperlipidemia which is clearly beyond the scope of the instantly disclosed/claimed invention. Please note that the term "prevent" is an absolute definition which means to stop from occurring and, thus, requires a higher standard for enablement than does "treating" or "reducing the risk", especially since it is notoriously well accepted in the medical art that the vast majority of

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afflictions/disorders suffered by mankind cannot be totally prevented with current therapies (other than certain vaccination regimes) - including preventing such disorders as atherosclerosis and hyperlipidemia (which are clearly not recognized in the medical art as being totally preventable conditions).

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is rendered vague and indefinite because it fails to recite any operative amount of the claimed herbals. Therefore, it is unclear if the plurality of herbals within the polyherbal preparation is/are each active agents therein, if each is/are merely some type of inert agents, and/or if each is/are is present in very small amounts representing perhaps a contaminant or residue. The claimed herbals within the polyherbal preparation are each deemed to be essential elements of the invention and, as such, they should be clearly defined (functionally) in the claim language itself. Accordingly, it is suggested that the phrase --an effective amount of-- be inserted before the word "mixture" (line 2) or, alternatively, that the limitations recited in any one of dependent claims 2, 4, or 5 be appropriately incorporated into claim 1, to clarify this ambiguity. In addition, as a formal matter, the genus "Termenalia" (as recited in claims 1 and 5) appears to be misspelled. Based upon an extensive search of the patent and non-patent literature, the apparent spelling of this genus is --Terminalia--.

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Claims 2 and 5 recite the limitation "the constituents" in lines 1-2 of each. There is insufficient antecedent basis for this limitation in these claims.

Claim 3 is rendered vague and indefinite by the phrase "A polyherbal preparation as claimed in claim 1 comprising *Rubia cordifolia* ..." because it is unclear by this recitation if Applicants are attempting to define some type of alternative embodiment or if the polyherbal preparation recited in claim 1 further comprises the herbals listed in claim 3. Accordingly, it is suggested that the term --further-- be inserted before "comprising" (line 1).

Claim 4 is rendered vague and indefinite by the phrase "A polyherbal preparation as claimed in claim 3 wherein the following constituents are added" (lines 1-2) because claim 3 does not recite that the herbal constituents listed therein are added. Therefore this phrase lacks adequate antecedent basis. Further, due to this lack of antecedent basis, it is unclear as to what the constituents of claim 4 are being added to - e.g., to the polyherbal preparation of claim 1, or to something else?

Claim 6 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite in that it fails to point out what is included or excluded by the claim language. This claim is an omnibus type claim. Accordingly, the limitations of claim 6 are completely unclear, as are the metes and bounds thereof.

The claims are free of the art. The prior art of record does not teach or reasonably suggest a polyherbal preparation (for treating/reducing the risk of atherosclerosis and hyperlipidemia) comprising the recited herbal constituents therein.

Conclusion

No claim is allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher R. Tate whose telephone number is (571) 272-0970. The examiner can normally be reached on Mon-Thur, 6:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Christopher R. Tate
Primary Examiner
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